

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

FILED
U. S. DISTRICT COURT
MIDDLE DISTRICT OF TENN
DEC - 5 2007

IN RE:

AREDIA and ZOMETA PRODUCTS
LIABILITY LITIGATION

MARIE TALLEY

vs.

NOVARTIS PHARMACEUTICALS
CORPORATION

Case No. 3 07 1 207

BY _____
DEPUTY CLERK

No. 3:06-MDL-01760

Judge Campbell

Magistrate Judge Brown

AMENDED COMPLAINT

Plaintiff files this Amended Complaint pursuant to the Order (DE. 785) entered on November 14, 2007 as follows:

01. Plaintiff, Marie Talley, is a citizen of the State of North Carolina. She resides in Mecklenburg County. A doctor prescribed her AREDIA and ZOMETA. As a result, she suffered osteonecrosis of the jaw.

02. Defendant Novartis Pharmaceuticals Corporation ("Novartis") is a Delaware corporation with its principal place of business located at One Health Plaza, East Hanover, New Jersey 07936-1080.

03. During all times relevant hereto, Novartis was in the business of manufacturing, marketing, distributing, promoting, testing, labeling, and selling AREDIA and ZOMETA.

04. This Court has *in personam* jurisdiction and venue. Novartis markets AREDIA and ZOMETA to physicians in Tennessee so that they will prescribe it to their patients in Tennessee.

Novartis distributes and sells AREDIA and ZOMETA to patients in Tennessee. Novartis compensates agents who “pitch” the drug to doctors here in Tennessee. Novartis sends instructional materials about the drugs and other Novartis products to patients and physicians in Tennessee. Novartis profits from health maintenance organizations administered in Tennessee. Patients in Tennessee remit a co-payment to pharmacists when purchasing Novartis products. Novartis profits from patients in Tennessee who use its medications. Novartis “resides” in the Middle District of Tennessee through its agents.

05 AREDIA and ZOMETA are bisphosphonates. The principal pharmacologic action of AREDIA and ZOMETA are inhibition of bone resorption. Bisphosphonates prevent and treat osteoporosis in post-menopausal women. Stronger forms of bisphosphonates are used in the management of advanced cancers that have metastasized to the bone. When bisphosphonates are given in cancer chemotherapy, drugs like AREDIA and ZOMETA are given intravenously and usually for longer periods.

06 Taking AREDIA and ZOMETA increase the risk of osteonecrosis of the jaw, including the maxilla (bone). Taking AREDIA and ZOMETA causes osteonecrosis of the bone. Novartis made labeling changes in September and October of 2003, but these changes were inadequate to warn consumers and remain so to this date.

COUNT I. STRICT LIABILITY

07. Novartis was engaged in the business of manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing AREDIA and ZOMETA in interstate commerce, which it then sold and distributed throughout the world. Therefore, Novartis is a manufacturer and this is a product liability action as

specified by Tennessee common law.

08. The Plaintiff was taking AREDIA and ZOMETA in a reasonably foreseeable manner.

09. AREDIA and ZOMETA reached her without a substantial change in condition.

10. She was not aware of and reasonably could not have discovered the specific danger of severe osteonecrosis associated with the use of AREDIA and ZOMETA.

11. AREDIA and ZOMETA increase the risk of osteonecrosis of the jaw. AREDIA and ZOMETA causes osteonecrosis of the jaw. Therefore, AREDIA and ZOMETA are “unreasonably dangerous / defective products” as specified by Tennessee common law due to Novartis’ failure to warn the Plaintiff.

12. These unreasonably dangerous / defective drugs increase the risk of osteonecrosis of the jaw. These drugs cause bisphosphonate-induced osteonecrosis. The Plaintiff has suffered osteonecrosis of the jaw. She has sustained compensatory damages in an amount to be proven at trial.

13. Novartis also acted recklessly as defined by the Tennessee Supreme Court in *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896 (Tenn. 1992). Therefore the Plaintiff seeks imposition of punitive damages in order to punish Novartis and deter other drug companies from the same wrongdoing.

COUNT II. NEGLIGENCE

14. Novartis owed the Plaintiff a common law duty to use reasonable care in manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, and advertising of AREDIA and ZOMETA. This duty included a warning about the danger of bisphosphonate-induced osteonecrosis.

15. Novartis breached that duty of care in one or more of the following respects:

- a. Failing to test and inspect AREDIA and ZOMETA in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which they were designed, manufactured, and sold;
- b. Failing to utilize and implement a reasonably safe design in the manufacture of AREDIA and ZOMETA;
- c. Failing to manufacture AREDIA and ZOMETA in a reasonably safe condition;
- d. Failing to warn the Plaintiff of the danger of bisphosphonate-induced osteonecrosis;
- e. Failing to label AREDIA and ZOMETA reasonably so as to warn the Plaintiff of the danger of bisphosphonate induced osteonecrosis; and
- f. Manufacturing AREDIA and ZOMETA, which are unreasonably dangerous / defective drugs.

16. Furthermore, Novartis is guilty of negligence *per se*. Novartis violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and the Sherman Food, drug and Cosmetic Law, as well as other applicable laws, statutes, and regulations. Novartis' acts and omissions constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331. This is negligence *per se*.

17. Novartis failed to meet the standard of care set forth by the following statutes and regulations. Legislators enacted these statutes and regulations for the benefit of a specific class of citizens. The Plaintiff is part of this class. Therefore, Novartis is negligent *per se* in the following respects:

- (a) The labeling lacked adequate information on the use of the drugs AREDIA and ZOMETA (21 C.F.R. Section 201.56[a] and [d]);

- (b) The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitations, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drugs (21 C.F.R. 201.57[e]);
- (c) There was inadequate information for patients for the safe and effective use of Novartis' drugs (21 C.F.R. 201.57[f][2]);
- (d) There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Novartis' drugs (21 C.F.R. 201.57[f][2]); and
- (e) The labeling was misleading and promotional (21 C.F.R. 201.56[b]).

18. Novartis' negligence is the proximate cause of all damages. The Plaintiff suffered osteonecrosis of the jaw. She has sustained compensatory damages in an amount to be proven at trial.

WHEREFORE, the Plaintiff requests that a jury be impaneled and that this Court award compensatory damages and punitive damages in an amount specified by the jury.

Respectfully submitted,



ROBERT G. GERMANY, MSB #4800
PITTMAN, GERMANY, ROBERTS
& WELSH, L.L.P.
410 South President Street (39201)
Post Office Box 22985
Jackson, Mississippi 39225-2985
Telephone: 601-948-6200
Facsimile: 601-948-6187

And

F. DULIN KELLY, TNB #04085
CLINTON L. KELLY, TNB #16171
ANDY L. ALLMAN, TNB #17857
KELLY, KELLY & ALLMAN
629 East Main Street
Hendersonville, TN 37075
Telephone: 615-824-3703
Facsimile: 615-822-7339

And

C. PATRICK FLYNN, TNB #2718
MICHAEL K. RADFORD, TNB #12763
FLYNN and RADFORD ATTORNEYS, P C.
Seven Springs I, Suite 150
320 Seven Springs Way
Brentwood, TN 37207
Telephone: 615-370-9448
Facsimile: 615-370-9313

CERTIFICATE OF SERVICE

I, Robert G. Germany, hereby certify that I have on this 4 day of December, 2007 served, via United States Mail, postage pre-paid, a true and correct copy of the foregoing pleading to the following:

Andy L. Allman
Kelly, Kelly & Allman
629 E. Main Street
Hendersonville, TN 37075
(615) 824-3703
kellykellyallman@comcast.net

Mary F. April
The Coates Law firm
12012 S Shore Boulevard Suite 107
Wellington, FL 33414
(561) 333-4911
(561) 333-4988 (fax)
mapril@coateslawfirm.com

Earl B. Austin
Baker Botts, LLP
2001 Ross Ave., Suite 900
Dallas, TX 75201-2980
(214) 953-6500
(214) 953-6503 (fax)
earl.austin@bakerbotts.com

Catherine R. Baumer
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)
cbaumer@spriggs.com

Russel H. Beatie
Beatie & Osborn, LLP
521 Fifth Ave., Suite 3400
New York, NY 10175
(212) 888-9000
(212) 888-9664 (fax)
bhunter@bandolaw.com

Richard C. Bennett
Bennett, Johnson & Galler
1901 Harrison St., 16th Floor
Oakland, CA 94612
(510) 444-5020
(510) 835-4260 (fax)
richardb@bjglawyers.com

Bradford Berge
Holland & Hart, LLP
110 N. Guadalupe Suite 1
P O. Box 2208
Santa Fe, NM 87504-2208
(505) 988-4421
Fax: (505) 983-6043
bberge@hollandhart.com

Adam J. Berger
Schroeter, Goldmark & Bender
810 Third Avenue Suite 500
Seattle, WA 98104
(206) 622-8000
(206) 682-23005 (fax)
berger@sgb-law.com

Turner W. Branch

The Branch Law Firm
2025 Rio Grande Boulevard, NW
Albuquerque, NM 87104
(505) 243-3501
Fax: (505) 243-3534
tbranch@branchlawfirm.com

Robert W. Briley

Briley Law Group, PLLC
511 Union Street, Suite
1610 Nashville, TN 37219
(675) 986-2684
rob@brileylaw.com

James A. Bruen

Farella, Braun & Martel, L.L.P.
235 Montgomery Street, 30th Floor
San Francisco, CA 94104
(415) 954-4400
(415) 954-4736 (fax)
jbruen@fbm.com

Michael Campbell

Holland & Hart, LLP
110 N. Guadalupe, Suite I
P.O. Box 2208
Santa Fe, NM 87504-2208
(505) 988-4421
(505) 983-6043 (fax)
mcampbell@hollandhart.com

Myers Carroll Cayer

Terrell, Hogan
233 E. Bay Street, Suite 800
Jacksonville, FL 32202-3451
(904) 632-2424
(904) 632-0549 (fax)
cayer@terrellhogan.com

Eugene C. Brooks, IV

Brooks Law Firm
P.O. Box 9545
Savannah, GA 31412-9545
(912) 233-9696
(912) 232-8690
gbrooks@brooks-law.com

Eric J. Buhr

Reed Smith, LLP
355 S. Grand Avenue Suite 2900
Los Angeles, CA 90071-1514

Andrew J. Carboy

Sullivan, Papain, Block, McGrath &
Cannavo
120 Broadway, 18th Floor
New York, NY 10271
(212) 732-9000
(212) 266-4141 (fax)
acarboy@triallaw1.com

Howard K. Coates, Jr.

The Coates Law Firm
12012 S Shore Boulevard, Suite 107
Wellington, FL 33414
(561) 333-4911
(561) 333-4988 (fax)
hcoates@coateslawfirm.com

Andrew L. Colocotronis
Baker, Donelson, Beannan, Caldwell &
Berkowitz, P.C.
900 South Gay Street
2200 Riverview Tower
Knoxville, TN 37902
aolocotronis@bakerdonelson.com

Jim C. Curtis
Kemp Smith, LLP
221 N. Kansas St., Suite 1700
El Paso, TX 79901
(915) 533-4424
(915) 546-5360 (fax)
jcurtis@kempsmith.com

Vicente de la Cruz
The Branch Law Firm
2025 Rio Grande Boulevard, NW
Albuquerque, NM 87104
(505) 243-3500
Fax: (505) 243-8319
vdelacruz@branchlawfirm.com

Jeffrey A. Dickey
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5853
(202) 602-1639 (fax)
jdickey@spriggs.com

Penelope A. Dixon
Carlton Fields, P.A.
P.O. Box 3239
4221 W. Boy Scout Blvd, Suite 1000
Tampa, FL 33601-3239
(813) 223-7000
(813) 229-4133 (fax)
pdixon@carltonfields.com

Brian J. Connelly
Gould, Cooksey, Fennell, Barkett,
O'Neill & Marine
979 Beachland Boulevard
Vero Beach, FL 32963-1688
(865) 549-7000
(772) 231-2020 (fax)

Paul Anthony Daniels
Teague, Rotenstreich & Stanaland
P.O. Box 1898
Greensboro, NC 27402-1898
(336) 272-4810
Fax: (336) 272-2448
pad@trslaw.com

Annesley H. Degaris
Cory, Watson, Crowder & Degaris, P.C.
2131 Magnolia Ave.
Birmingham, AL, 35205
(205) 328-2200
(205) 324-7896(fax)
adegarlis@cwcd.com

Pamela J. Diedrich
Mason, Cawood & Hobbs, PA
69 Franklin Street
Annapolis, MD 21401
(410) 269-6620
(410) 269-5452 (fax)
pjd@mkc-law.com

James W. Dodson
Law Offices of James W. Dodson
1259 Myrtle Avenue South
Clearwater, FL 33756
(727) 446-0840
(727) 446-0850
jim@jwdodsonlaw.com

Scott Eldredge

Burg, Simpson, Eldredge, Hersh &
Jardine, P.C.
40 Inverness Drive, East
Englewood, CO 80112
(303)792-5595
(303)708-0527 (fax)
seldredge@burgsimpson.com

Deirdre C. Gallagher

Spencer, Fane, Britt & Browne, LLP
One North Brentwood Blvd Suite 1000
Clayton, MO 63105-3925
(314) 863-7733
(314) 862-4656
Tampa, FL 33601-3239
dgallagher@spencerfane.com

Robert G. Germany

Pittman, Germany, Roberts & Welsh, LLP
410 S. President Street
Jackson, MS 39201
(601) 948-6200
(601) 948-6187 (fax)
rgg@pgrwlaw.com

David R. Gronbach

Moynahan & Minnella, LLC
141 T. Main Street
Waterbury, CT 06722
(203) 573-1411
(203) 757-9313 (fax)
dgronbach@moynahanlawfirm.com

Thomas W. Hayde, Jr.

Spencer, Fane, Britt & Browne, LLP
One North Brentwood Blvd, Suite 1000
Clayton, MO 63105-3925
(314) 863-7733
(314) 862-4656
thayde@spencerfane.com

Donald W. Fowler

Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)
dfowler@spriggs.com

Edward W. Gerecke

Carlton Fields, P.A.
P.O. Box 3239
4221 W. Boy Scout Blvd., Ste. 1000
(813) 223-7000
(813) 229-4133 (fax)
egerecke@carltonfields.com

Alvin M. Gomez

Gomez Law Group
8910 University Center Lane, Suite 550
San Diego, CA 92122
(858) 552-0000
(858) 552-8505 (fax)
agomez@thegomezlawgroup.com

Peter H. Gunst

Astrachan, Gunst & Thomas, P.C.
217 E. Redwood Street, Suite 2100
Baltimore, MD 21202
(410) 783-3550
(410) 783-3530
pgunst@agtalawyers.com

Frederick G. Helmsing, Jr.

McDowell, Knight, Roedder & Sledge, LLC
63 S. Royal St., Suite 900
P.O. Box 350
Mobile, AL 36602
(251) 432-5300
(251) 432-5302 (fax)
fhelmsing@mcdowellknight.com

Joe G. Hollingsworth
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)
jhollingsworth@spriggs.com

Robert E. Johnston
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)
rjohnston@spriggs.com

Clinton L. Kelly
Kelly, Kelly & Allman
629 E. Main Street
Hendersonville, TN 37075
kellykellyallman@comcast.net

James B. King
Keefe, King & Bowman, P.S.
West 601 Main Avenue, Suite 1102
Spokane, WA 99201
(509) 624-8988
(509) 623-1380
jking@kkbowman.com

Katharine R. Latimer
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)
klatimer@spriggs.com

Fred Cromwell Isaac
Foerster, Isaac & Yeikes, P.A.
2468 Atlantic Boulevard
Jacksonville, FL 32207
US
(904) 396-3160
(904) 348-0927 (fax)
fisaac@fly-attorneys.com

Thomas Q. Keefe, Jr.
6 Executive Woods Court
Belleville, IL 62226
(618) 236-2221
(618) 236-2194
debbie@tqkeefe.com

Fred Dulin Kelly
Kelly, Kelly & Allman
629 E. Main Street
Hendersonville, TN 37075
kellykellyallman@comcast.net

Dan E. LaBelle
Halloran & Sage, LLP
315 Post Road West
Westport, CT 06880
(203) 227-2855
(203) 227-6992 (fax)
labelle@halloran-sage.com

Dara Lovitz
Anapol, Schwartz, Weiss, Cohan,
Feldman & Smalley, P.C.
1710 Spruce Street
Philadelphia, PA 19103
(215) 790-4577
dlovitz@anapolschwartz.com

Roy Lenard Mason

Mason, Cawood & Hobbs, PA
69 Franklin Street
Annapolis, MD 21401
(410) 269-6620
(410) 269-5452 (fax)
rmason@mkc-law.com

Michael L. McCluggage

Wildman Harrold
225 W. Wacker Drive, Suite 3000
Chicago, IL 60606
(312) 201-2000
(312) 201-5555 (fax)
mccluggage@wildmanharrold.com

Philip J. Miller

Beatie & Osborne
521 Fifth Avenue, 34th Floor
New York, NY 10175
(212) 888-9000
(212) 888-9664 (fax)
pmiller@bandolaw.com

Melanie H. Muhlstock

Parker & Waichman, LLP
111 Great Neck Road, 1st Floor
Great Neck, NY 11021-5402
(516) 466-6500
mmuhlstock@yourlawyer.com

Nicholas S. Nassif

3055 Wilshire Blvd., Ste. 900
Los Angeles, CA 90010
(213) 736-1899
nsnassif@pacbell.net

Stephen E. Matasich

Day Ketterer, Ltd.
Millennium Center
200 Market Ave., N., Suite 300
P.O. Box 24213
Canton, OH 44701-4213
(330) 455-0173
(330) 455-2633 (fax)
sematasich@dayketterer.com

Ronald E. McMillan

Watkins & Eager
P. O. Box 650
400 E. Capitol Street, Ste. 300
Jackson, MS 39205
(601) 948-6470
rmcmillan@watkinseager.com

Mildred M. Morris

Watkins & Eager
P. O. Box 650
400 E. Capitol Street, Ste. 300
Jackson, MS 39205
(601) 948-6470
mmorris@watkinseager.com

Michael T. Mullen

Paul B. Episcopo, LLC
77 W. Washington Street, Suite 300
Chicago, IL 60602
(312) 782-6636
mtm@episcopeltltd.com

Sarah Olson

Wildman Harrold
225 W. Wacker Drive, Suite 3000
Chicago, IL 60606
(312) 201-2000
(312) 201-5555 (fax)
olson@wildmanharrold.com

Daniel A. Osborn

Beatie & Osborn
521 Fifth Avenue, 34th Floor
New York, NY 10175
(212) 888-9000
(212) 888-9664 (fax)
dosborn@bandolaw.com

Peter G. Pappas

Nexsen, Pruet, Adams & Kleezner, PLLC
P.O. Box 3463
Greensboro, NC 27402
(336) 373-1600
(336) 273-5357 (fax)
ppappas@npaklaw.com

Heather A. Pigman

Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)
hpigman@spriggs.com

Crymes G. Pittman

Pittman, Germany, Roberts & Welsh, LLP
410 S. President Street
Jackson, MS 39201
(601) 948-6200
(601) 948-6187 (fax)
cgp@pgrwlaw.com

Joseph E. Roberts, Jr.

Pittman, Germany, Roberts & Welsh, LLP
410 S. President Street
Jackson, MS 39201
(601) 948-6200
(601) 948-6187 (fax)
jer@pgrwlaw.com

Mark N. Osborn

Kemp Smith, LLP
221 N Kansas Street, Suite 1700
El Paso, TX 79901
(915) 533-4424
(915) 546-5360 (fax)
mosborn@kempsmith.com

Jerrold S. Parker

Parker & Waichman, LLP
111 Great Neck Road, 1st Floor
Great Neck, NY 11021-5402
(516) 466-6500
jerry@yourlawyer.com

Michael Pilarz

Law Offices of Michael Pilarz
237 Main Street, Suite 650
Buffalo, NY 14203-2713
(716) 852-4351
(716) 852-6457 (fax)
law@pilarz.com

Michael A. Pohl

Law Office of Michael A. Pohl
11111 Katy Freeway, Suite 910
Houston, TX 77079
(713) 652-0100
(713) 650-0687 (fax)
pohlatty@aol.com

Thomas E. Rubbert

Law Offices of Thomas E. Rubbert
790 E. Colorado Blvd., 9th Fl.
Pasadena, CA 91101
(626) 793-2773
rubbertlaw@aol.com

Christopher A. Seeger
Seeger Weiss, LLP
550 Broad Street, Suite 920
Newark, NJ 07102
(973) 639-9100
(973) 639-9393 (fax)
eseeger@seegerweiss.com

Michael F. Seelie
Michael E. Seelie, P.A.
2468 Atlantic Boulevard
Jacksonville, FL 32210
(904) 858-1895
(904) 858-1898 (fax)
mseelie@comcast.net

Yanika C. Smith
Baker, Donelson, Bearman, Caldwell
& Berkowitz, PC
Commerce Center, Suite 1000
211 Commerce Street
Nashville, TN 37201
(615) 726-5600
ysmith@bakerdonelson.com

Ethan D. Stein
Gibbons, Del Deo, Dolan, Griffinger
& Veccione
One Pennsylvania Plaza, 37th Floor
New York, NY 10119-3701
(212) 649-4700
(212) 333-5980 (fax)
estein@gibbonslaw.com

Peter D. Tarpey
Paul B. Episcopo, LLC
77 W. Washington St., Suite 300
Chicago, IL 60602
(312) 782-6636
pdt@episcopeltltd.com

Edward M. Sledge, III
McDowell, Knight, Roedder & Sledge, LLC
63 S. Royal St., Suite 900
P.O. Box 350
Mobile, AL 36602
(251) 432-5300
esledge@mcdowellknight.com

Gregory S. Spizer
Anapol, Schwartz, Weiss, Cohan,
Feldman & Smalley, P.C.
1710 Spruce Street
Philadelphia, PA 19103
(215) 790-4578
(215) 875-7722 (fax)
gspizer@anapolschwartz.com

Lewis T. Stoneburner
Cantor Arkema, P.C.
Bank of America Center
1111 E. Main Street
P.O. Box 561
Richmond, VA 23218-0561
(804) 644-1400
lstoneburner@cantorarkema.com

Linda Laurent Thomas
Thomas & Wan, LLP
909B Est Main
Houston, TX 77006
(713) 529-1177
(713) 529-1116 (fax)
lthomas@thomasandwan.com

John O. Threadgill

Threadgill Law Firm
9724 Kingston Pike, Suite 701
Knoxville, TN 37922
(865) 588-4100
(865) 588-4120
jthreadgill@threadgillfirm.com

Bart T. Valad

Law Firm of Bart T. Valad, PLLC
3863 Plaza Drive
Fairfax, VA 22030
(703) 352-4800
(703) 352-4820 (fax)
bvalad@valadlaw.com

Jenny M. Virden

Chapman, Lewis & Swan
P. O. Box 2801
Madison, MS 39130
(601) 605-9081
jvirden@bellsouth.net

John S. Wallach

100 South Brentwood Blvd. Suite 300
St. Louis, MO 63105-1635
(314) 241-2500
(314) 241-2215 (fax)
john@wallachwolff.com

Wallace B. Wason, Jr.

Cantor Arkema, P.C.
Bank of America Center
1111 E. Main St.
P.O. Box 561
Richmond, VA 23218-0561
(804) 644-1400
wwason@cantorarkema.com

Windle Turley

Law Offices of Windle Turley, P.C.
1000 Turley Law Center
6440 N. Central Expressway
Dallas, TX 75206
(214) 691-4025
Toll-free: 800-692-4025
(214) 361-5802 (fax)
windle@wturley.com

John Vecchione

Law Firm of Bart T. Valad, PLLC
3863 Plaza Drive
Fairfax, VA 22030
(703) 352-4800
(703) 352-4820 (fax)
jvecchione@valadlaw.com

Stephanie D. Wade

Baker Botts, LLP
2001 Ross Ave., Suite 900
Dallas, TX 75201-2980
(214) 953-6500
(214) 953-6503 (fax)
stephanie.wade@bakerbotts.com

Michelle W. Wan

Thomas & Wan, LLP
909B West Main
Houston, TX 77006
(713) 529-1177
(713) 529-1116 (fax)
mwan@thomasandwan.com

Derrick K. Watson

Farella, Braun & Martel, L.L.P.
235 Montgomery St., 30th Floor
San Francisco, CA 94104
(415) 954-4400
(415) 954-4736 (fax)
dwatson@fbm.com

John C. Weisensell
Bernlohr & Wertz
301 Nantuck Building
23 S. Main Street
Akron, OH 44308
(330) 434-1000
(330) 434-1001 (fax)
jack@b-wlaw.com

William P. Woods
Woods & Woods, LLP
208 NB 4th Street
Evansville, IN 47708-1353
(812) 426-7205
(812) 426-7207 (fax)
bwoods@woodslawyers.com

Roxanne M. Wilson
Reed Smith LLP
355 S. Grand Avenue, Suite 2900
Los Angeles, CA 90071-1514
(213) 457-8000
(213) 457-8080 (fax)
rwilson@reedsmith.com

Alicia M. Wyler
Day Ketterer, Ltd.
Millennium Center, Suite 300
200 Market Ave., North
P.O. Box 24213
Canton, OH 44701-4213
(330) 455-0173
(330) 455-2633 (fax)
amwyler@dayketterer.com

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